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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,543	07/27/2001	Konrad Basler	Q-60361	9256

7590 11/30/2004

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,543	BASLER ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71,73,75,77 and 79-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71,73,75,77 and 79-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 71, 73, 75, and 77 remain rejected, and claims 79-82 are rejected under 35 U.S.C. 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 6-14-04.

3. Applicant's arguments filed 9-14-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the claims have been amended to make clear that the claimed polypeptides do not contain both the HD1 and HD2 domains at the same time, and further new Claims 79-82 require that the polypeptides bind to Doll or β-cat. Applicants respectfully submitted that that the Examiner's rejection should be withdrawn in view of these amendments and the abundant support in the specification for peptides. Contrary to Applicant's assertions, it remains that the scope of the instant claims encompasses wherein the polypeptides contain both the HD1 and HD2 domains, see claim 71 as currently amended which recites:

An isolated polypeptide comprising:

(i) a peptide consisting of amino acids 177 to 204 of SEQ ID NO:15,

or

(ii) a peptide consisting of amino acids 349 to 383 of SEQ ID NO:15,

or

-wherein said isolated polypeptide does not comprise both of said peptide (i) and (ii), and said isolated polypeptide inhibits tcf-driven luciferase activity in colon cancer cells.

After sections (i) and (ii) of claim 71 it recites "**or** *(emphasis added)* wherein said isolated polypeptide does not comprise both of said peptide (i) and (ii), and said isolated polypeptide inhibits tcf-driven luciferase activity in colon cancer cells." It remains that the isolated polypeptide of claim 71 may "comprise" peptide (i) or (ii), and further wherein said isolated polypeptide may comprise both peptide (i) and (ii). Therefore, Applicant's arguments that the claims as currently amended overcome the prior rejection is not persuasive since the claimed polypeptides may contain both the HD1 and HD2 domains at the same time.

In the Office Action mailed 6-14-04, it was the Examiner's position that the specification only provides written description for polypeptides "consisting of" residues 177-204, 349-383 and 199-392, and that these species are not representative of the claimed genus of polypeptides "comprising" the claimed sequence because the genus is highly variant, the specification does not provide a description of which polypeptides within the genus have the function claimed and there is no reliable correlation between the structure provided (the sequence of peptide fragments) and the claimed function (inhibits tcf-driven luciferase activity in colon cancer cells). In response Applicants argued that it is homology regions HD1 and HD2, which act to inhibit tcf-driven luciferase activity in colon cancer cells, and the remaining sequences, which may be present, are not critical. Moreover, According to Applicants, the Examiner contended that this argument is not persuasive because Applicants argue in response to the prior art rejection (see

below) that additional sequence can actually eliminate the claimed function. However, according to Applicants the claims have been amended to make clear that the claimed polypeptides do not contain both the HD1 and HD2 domains at the same time, and further new Claims 79-82 require that the polypeptides bind to Doll or β-cat. Applicants respectfully submitted that that the Examiner's rejection should be withdrawn in view of these amendments and the abundant support in the specification for peptides comprising either HD1 or HD2 for binding Lgs partner proteins Doll and β-cat as negative regulators of the Wnt pathway by inhibiting tcf-driven luciferase activity in colon cancer cells.

Contrary to Applicant's assertions it is noted that although Applicants have amended the instant claims to recite that the claimed polypeptide do not contain both the HD1 and HD2 domains at the same time, it is clear that the isolated polypeptides of the claimed invention may "comprise" additional sequence that may function to eliminate the claimed function. Moreover, since it is unclear what amino acid sequence structural information may be either added or removed from the polypeptides according to the present invention such that the remaining polypeptide is 90% identical to the peptides of the present invention, and retains the ability to bind Doll or β-cat, Applicants have not provided a clear nexus between the amino acid sequence structure of the claimed polypeptides and the corresponding function of the broad genus of polypeptides encompassed by the instant claims. Additionally, it is clear that apart from further experimentation the skilled artisan would not be able to predict the structures of the full scope of compounds encompassed by the instant claims.

As stated in the prior Office Action, the instant claims encompass full length polypeptides from other species, mutated versions of the full length polypeptide, polypeptides

encoded by allelic variants and splice variants, derivatives and variants of these polypeptides, polypeptides comprising a fragment of unspecified length (e.g. even one amino acid residue of residues 199-392 of SEQ ID NO:15). Applicants have previously provided data that demonstrate (see for example figure 15B) that polypeptides comprising the specifically claimed sequences do not necessarily also have the function of inhibiting tcf-driven luciferase activity in colon cancer cells. For example, additional sequences can interfere with this activity and, therefore, there is no direct correlation between the claimed structure and the claimed function. The specification has provided written description for the specific sequences recited in the claims, however, there is not sufficient written description to determine which polypeptides comprising these sequences or comprising peptides with 90% identity to these sequences meet the functional limitations.

See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

4. Claims 71, 73, 75, and 77 remain rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/57188), for the reasons of record set forth in the prior Office Action.

5. Applicant's arguments filed 9-14-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Tang et al. discloses a protein having all HDs of human Lgs, and thus differs from the polypeptides of the present invention which do not contain both HD1 and HD2. Contrary to Applicant's assertions it is noted that the scope of the instant claims encompasses polypeptides which contain both HD1 and HD2. See claim 71 which recites:

An isolated polypeptide comprising:

(i) a peptide consisting of amino acids 177 to 204 of SEQ ID NO:15,

or

(ii) a peptide consisting of amino acids 349 to 383 of SEQ ID NO:15,

or

-wherein said isolated polypeptide does not comprise both of said peptide (i) and (ii), and said isolated polypeptide inhibits tcf-driven luciferase activity in colon cancer cells.

Therefore, the isolated polypeptide of Tang et al. that is 99.4% identical to amino acid residues 1-1392 of SEQ ID NO: 15 anticipates the claimed invention.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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